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There is uncertainty about whether women older than age 65 should undergo screening mammography. Although screening mammography may benefit some elderly women through the detection of early breast cancers, it may harm other women through false positive diagnoses and the detection of clinically insignificant lesions. This research study involves the design and implementation of a data analysis of HCFA Medicare billing claims linked with National tumor registry data from the Surveillance Epidemiology and End Results (SEER) program. The specific aims of this research will evaluate 1) differences in breast cancer mortality, 2) differences in breast cancer treatment and 3) difference in breast cancer tumor attributes between women who were screened and those who were not. In the second year of this grant the PI focused on validating that the Medicare claims are accurate for determining screening mammography. She obtained data from three Breast Cancer Surveillance Consortium Registries (New Mexico, Seattle, and San Francisco) that prospectively collect screening information, has linked this with the Medicare/SEER data, and is currently determining whether Medicare claims accurately assess mammography utilization. Following completion of this validation study (6 months) the PI will analyze differences in breast cancer treatments, tumor characteristics and mortality based on screening.

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INTRODUCTION

There is uncertainty about whether women older than age 65 should undergo screening mammography. Although screening mammography may benefit some elderly women through the detection of early breast cancers, it may potentially harm other women through false positive diagnoses and the detection and surgical treatment of clinically insignificant lesions. This research study involves the design and implementation of a data analysis of HCFA Medicare billing claims linked with National tumor registry data from the Surveillance Epidemiology and End Results (SEER) program. The specific aims of this research will evaluate the outcomes associated with the use of screening mammography in elderly women.

The first step of this project (described as Specific Aim 1: Validating Algorithm for Determining Screening History) is to determine whether Medicare physician claims can be used to accurately distinguish screening from diagnostic mammography among elderly women with breast cancer. Our research efforts to date have focused on this aim, however, in the process of completing this aim, we have cleaned the data sets that will be used for the remainder of the specific aims. Of note, while we originally had planned to complete this aim by comparing the Medicare data to a "gold standard" based on chart review, we changed our gold standard to include information from an NCI sponsored consortium of mammography registries in the U.S., the Breast Cancer Surveillance Consortium. In the revised statement of work #3, I specified that in order to validate that the Medicare data are accurate for the determination of screening mammography, I would not do chart review, but rather would obtain data from a mammography registry. This change was made as the mammography registry prospectively collects information of the use of screening mammography and patient symptoms and was therefore more appropriate for use as a gold standard to validate the accuracy of the Medicare claims. Three of the BCSC sites link with SEER tumor registries and thus overlap the data I obtained using the SEER-Medicare data. Thus the same women are included in both the registry data and SEER-Medicare data and allow me to compare the characterization of mammography in each data set.

The numbering below refers to the Revised Statement of Work.

STUDIES and RESULTS

SOW #1: Obtain Health Care Financing Administration/SEER Tumor Registry Data
The linked Medicare HCFA/SEER database describing Medicare claims through 1998 and breast cancer cases through 1996 was obtained, and data cleaning of this complex administrative database is complete.

SOW #2: Detailed study Design and project development for Specific Aim #1
a) Develop Algorithm that will be used for determining the predictor variable of screening mammography utilization (in women with breast cancer)
This has been completed. *Using the Medicare data, and BCSC data (Breast Cancer Surveillance Consortium)* all women and all mammograms will be characterized within each database separately based on their use of mammography in the 1-6 years prior to a diagnosis of cancer (similar algorithm used for aged-matched women without cancer). Each woman's mammographic screening history will be characterized as follows:

Woman level

- 1) Not Screened (women with no screening mammogram)
- 2) First screening mammogram (or first within 5 years)
- 3) Screened 1-2 years before cancer detected (=frequently screened).
- 4) Screened 2-3 years before cancer detected.
- 5) Screened 3-5 years before cancer detected

For women in Group 2 (women who have had their first screening mammogram around the time of breast cancer diagnosis) it is crucial that we differentiate whether these are truly screening or diagnostic mammograms, and thus a more detailed algorithm will be used to characterize these mammograms as their likelihood of being obtained for screening or diagnostic purposes.

Mammogram level

- 1) Screening
- 2) Probably screening
- 3) Screening with a breast mass
- 4) Probably diagnostic
- 5) Diagnostic

The Validation study described in Specific Aim #1 will evaluate how well the *Medicare data* characterizes each group, compared to the "gold standard" characterization of screening mammography utilization from the *BCSC*. We have attached the method that will be used to characterize mammograms using the *BCSC* data (Attachment A) and Medicare data (attachment B). In summary, the *BCSC* data relies on an assessment of physical symptoms, referring clinician and radiologists estimation of whether the mammogram was obtained for screening or diagnostic purposes, whereas the Medicare data relies on the use of billed procedures and M.D. visits to determine if mammograms were obtained for screening or diagnostic purposes.

b) Develop mammography registry abstraction algorithm.

We generated a list of variables to be obtained on all women with cancer (n = 4232) from the three participating Mammography BCSC registries and these data will be used to characterize mammograms and women as screened or not screened with mammography as described above (Attachment C).

SOW #3 Validating Algorithm for Determining Screening History

a) Analyze HCFA claims

In order to prepare the Medicare/SEER mammography data for comparison with our external dataset, several steps were taken. The first was to use the SEER data to find the breast cancer patients that matched our inclusion criteria: at least age 66 at Breast Cancer diagnosis (BC Diagnosis), date of BC Diagnosis after 1992, and no months of HMO coverage prior to BC Diagnosis. We subsequently used diagnostic/procedural codes in the Medicare data to find the mammograms for each woman. However, since the number of mammograms a woman had in a given time period would influence the screening/diagnostic designation, we had to exercise caution that we were not including spurious encounters coded as having a mammogram (if, for example there was a claim for a mammogram that had been rejected and was duplicated in an accepted claim). In order to apply the algorithm for determination of screening/diagnostic mammogram, we needed to find the breast cancer related procedural/diagnostic codes in the Medicare data and quantify their relation in time with both mammograms and BC Diagnosis. Throughout this process, we have had use various techniques (graphical, descriptive statistics) to assess the validity and learn the peculiarities of the Medicare data, especially in the area of coding anomalies and duplicated records.

We used both procedural and diagnostic codes (ICD9 and CPT) from the NCH (National Claims History) file dataset, the OUTSAF (outpatient), and the MEDPAR (inpatient) dataset to determine both the breast cancer patient's mammogram and breast cancer history. The decision to use all three datasets came from information gathered from an NIH seminar focused on doing analyses of SEER-Medicare data. Mammograms were identified by the CPT codes 76090, 76091 and 76092, and batteries of ICD9 and CPT codes were used to identify breast cancer related diagnoses / procedures. Some examples of the (procedural) ICD9 codes we used were: 85.11, 85.12 (breast biopsy), 85.87 (mammaryplasty). We used CPT codes such as 19100, 19101 (breast conserving surgery) and 19180 (mastectomy), among others. Among all the different breast cancer codes the patients had assigned to their visits, approximately 86% were diagnostic ICD9. We then identified the time difference (in days) between the different procedures/diagnoses and both mammograms and breast cancer diagnosis and found that the large majority of diagnoses/procedures occurred on the day of mammograms or soon (within three days) after. It should be noted that we took special care not to include redundant information between the OUTSAF and NCH datasets by comparing similar diagnoses / procedures that were linked temporally within an individual subject.

b) Choose women on whom the algorithm will be validated and obtain mammography registry on these women

During the second year of the grant, we generated a list of women with breast cancer from the SEER –Medicare data who also resided in one of the three BCSC mammography registry sites (i.e. San Francisco, New Mexico and Seattle). The list of mammography variables was compiled (attachment C) and sent to the three participating mammography registry sites. The 8-digit 'SEER Registry/ Patient Identification number' was also requested from each of the BCSC participating sites in order for us to link the mammography registry data with the Medicare data. All sites transmitted data to the in July 2001. The BCSC data was cleaned in the last few months of the second funding year.

c) Perform Statistical Analysis

Analysis of the BCSC data will be performed in the current third funding year (attachment D, E – method that will be used to compare data).

SOW #4: Perform literature reviews on variables that are associated with breast cancer

Literature reviews have been completed on issues relating to breast cancer in elderly women as well as issues focused on breast cancer in African American Women (attachment F). There has recently been some excellent work on the assessment of co-morbidities and methods to adjust for them using Medicare data, and thus we will rely on much of the work by Klabunde, et al (included in the list of references) to perform co-morbidity adjustment.

Additional Work

The PI was based in London the first year of funding, and designed a study to compare the performance of screening mammography in the US and UK. Over the second year, she obtained data for two US data sources to compare with data she obtained for the UK National Health Service Breast Cancer Screening Program. These data were obtained from the BCSC (describing approximately 1 million mammograms), and from the Center for Disease Control and Prevention National Breast and cervical cancer Early Detection Program (describing approximately 700,000 mammograms). During Fund year 2, the analyses plans were devised, variables were defined, and data cleaning of these large datasets were begun. The DOD will be acknowledged for all work that results from this analysis.

SIGNIFICANCE

If we find the Medicare physicians claims can be used to accurately determine whether women have undergone screening or diagnostic mammography, the SEER-Medicare database can be used to evaluate outcomes related to screening mammography utilization and these results may contribute to establishing guidelines for screening mammography in the elderly.

KEY RESEARCH ACCOMPLISHMENTS

- MEDICARE/SEER data cleaned, and relevant variables from this large complex dataset abstracted.
- Data was obtained and cleaned from three Breast Cancer Consortium Registries describing over 4,000 women with breast cancer. This data was linked with the data for the SEER/Medicare dataset.
- Algorithm developed for both the SEER/Medicare and BCSC data for differentiating between screening and diagnostic mammography.
- Literature reviews of breast cancer diagnosis and screening in elderly and non-Caucasian women.

REPORTABLE OUTCOMES

None

CONCLUSIONS

The second year of the project has been successful and achieved goals outlined in the Statement of Work. Analyses of the remainder of the aims are expected to proceed as originally planned.

Attachment A

Breast Cancer Surveillance Consortium Data: Algorithm to determine whether mammograms in BCSC were obtained for screening or diagnostic purposes.

Mammogram Level

SCREENING

MOST DEFINITELY SCREENED

- **Radiologist coded as screening**
 - II.13 Indication for exam (Code 1)
 - II.17 Routine Views (Code 1 thru Code 5) (?)
- **Patient reports no breast symptoms**
 - I.13 Breast Pain (Code 0)
 - I.11 Lump (Code 0)
 - I.12 Nipple Discharge (Code 0)
 - I.9 Symptoms (Code 0)
 - I.14 Other Symptoms (Code 0)
- **No prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are >9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are >9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 2,3,4)
(Use only if no information on II.10 & II.12)

PROBABLY SCREENING

MOST PROBABLY SCREENED

- **Radiologist coded as screening**
 - II.13 Indication for exam (Code 1)
 - II.17 Routine Views (Code 1 thru Code 5) (?)
- **Patient reports breast pain, no other breast symptoms**
 - I.13 Breast pain (Code 1 thru Code 5)
 - I.11 Lump (Code 0)
 - I.12 Nipple Discharge (Code 0)
 - I.9 Symptoms (Code 0)
 - I.14 Other Symptoms (Code 0)
- **No prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are >9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are >9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 2,3,4)
(Use only if no information on II.10 & II.12)

PROBABLY SCREENING (Screen with a breast mass)

PROBABLY SCREENED

- **Radiologist coded as screening**
 - II.13 Indication for exam (Code 1)
 - II.17 Routine Views (Code 1 thru Code 5) (?)
- **Patient reports specific breast symptoms (with or without breast pain)**
 - I.11 Lump (Code 1 thru Code 5) OR
 - I.12 Nipple Discharge (Code 1 thru Code5) OR
 - I.9 Symptoms (Code 1 thru Code5)
- **No prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are >9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are >9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 2,3,4)
(Use only if no information on II.10 & II.12)

PROBABLY DIAGNOSTIC

PROBABLY DIAGNOSTIC

- **Radiologist coded as screening**
 - II.13 Indication for exam (Code 1)
 - II.17 Routine Views (Code 1 thru Code 5) (?)
- **Patient reports specific breast symptoms (with or without breast pain)**
 - I.11 Lump (Code 1 thru Code 5) OR
 - I.12 Nipple Discharge (Code 1 thru Code 5) OR
 - I.9 Symptoms (Code 1 thru Code 5)
- **Prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are < 9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are <9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 2,3,4)
(Use only if no information on II.10 & II.12)

PROBABLY DIAGNOSTIC

PROBABLY DIAGNOSTIC

- **Radiologist coded as diagnostic**
 - II.13 Indication for exam (Code 2 thru Code 5)
 - II.18 Diagnostic Views (Code 1 thru Code 5) (?)
- **Patient reports no breast symptoms**
 - I.13 Breast Pain (Code 0)
 - I.11 Lump (Code 0)
 - I.12 Nipple Discharge (Code 0)
 - I.9 Symptoms (Code 0)
 - I.14 Other Symptoms (Code 0)
- **No prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are >9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are >9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 2,3,4)
(Use only if no information on II.10 & II.12)

DIAGNOSTIC

DEFINITELY DIAGNOSTIC

- **Radiologist coded as diagnostic**
 - II.13 Indication for exam (Code 2 thru Code 5)
 - II.18 Diagnostic Views (Code 1 thru Code 5) (?)
- **Patient reports no breast symptoms**
 - I.13 Breast Pain (Code 0)
 - I.11 Lump (Code 0)
 - I.12 Nipple Discharge (Code 0)
 - I.9 Symptoms (Code 0)
 - I.14 Other Symptoms (Code 0)
- **Prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are < 9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are <9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 2,3,4) (Use only if no information on II.10 & II.12)

DIAGNOSTIC

DEFINITELY DIAGNOSTIC

- **Radiologist coded as diagnostic**
 - II.13 Indication for exam (Code 2 thru Code 5)
 - II.18 Diagnostic View (Code 1 thru Code 5) (?)
- **Patient reports breast symptoms**
 - I.13 Breast Pain (Code 1 thru Code 5)
 - I.11 Lump (Code 1 thru Code 5) OR
 - I.12 Nipple Discharge (Code 1 thru Code 5) OR
 - I.9 Symptoms (Code 1 thru Code 5) OR
 - I.14 Other Symptoms (Code 1 thru Code 5)
- **No Prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are < 9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are <9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 1) (Use only if no information on II.10 & II.12)

DIAGNOSTIC

DEFINITELY DIAGNOSTIC

- **Radiologist coded as diagnostic**
 - II.13 Indication for exam (Code 2 thru Code 5)
 - II.18 Diagnostic View (Code 1 thru Code 5) (?)
- **Patient reports breast symptoms**
 - I.13 Breast Pain (Code 1 thru Code 5)
 - I.11 Lump (Code 1 thru Code 5) OR
 - I.12 Nipple Discharge (Code 1 thru Code5) OR
 - I.9 Symptoms (Code 1 thru Code5) OR
 - I.14 Other Symptoms (Code 1 thru Code 5)
- **Prior mammogram <9 months**
 - II.10 Exam Date or II.4 Information date & II.12 Preexam Date are < 9 months apart
 - I.4 Information date & I.20 Date of the last mammogram are <9 months apart (Use only if no information on II.10 & II.12)
 - I.19 Time since last mammogram (Code 1)
(Use only if no information on II.10 & II.12)

Attachment B

MEDICARE DATA: Mammogram Level

| |
|--|
| A) <u>NO MAMMOGRAMS</u> |
| B) <u>DIAGNOSTIC</u> <ul style="list-style-type: none">○ Mammogram billed as diagnostic(other than screening) AND○ Mammogram occurred within 1 month of breast cancer diagnosis AND○ <u>Mammogram occurred following a breast diagnostic procedure (biopsy) OR</u> <u>Mammogram occurred following breast treatment procedure (lumpectomy)</u> |
| C) <u>ONLY PERICANCER MAMMOGRAM</u> <ul style="list-style-type: none">○ Mammogram billed as diagnostic/bilateral○ Mammogram occurred <u>within 3 months</u> of breast cancer diagnosis○ Mammogram billed only, no breast diagnostic procedure prior to the mammogram○ Mammogram billed only, no breast treatment procedure prior to the mammogram○ <u>No prior mammograms</u> <p>*This group is the 'problem group' using Medicare data. The goal is for some women to use 'Woman level' data to determine within this group, whether women were 'Screened', For example, if women have At least one screening mammogram within 3 years of breast cancer diagnosis, or a mammogram > 9 months prior to breast cancer diagnosis they will be considered screened.</p> |
| D) <u>SCREENING</u> <ul style="list-style-type: none">○ Mammogram billed as <u>screening</u>○ Mammogram billed only, no breast diagnostic procedure○ Mammogram billed only, no breast treatment procedure○ No mammogram within 9 months of this mammogram |
| E) <u>SCREENING + DIAGNOSTIC = SCREENING</u> <ul style="list-style-type: none">○ Two closely spaced mammograms <u>within 90 days of each other</u><ul style="list-style-type: none">▪ First mammogram = Screening▪ Second mammogram = Diagnostic <p>Women will be considered screened as having both Screening and Diagnostic</p> |

Attachment C

List of Mammography variables for the ' Validation study' Breast Cancer Surveillance Consortium

I. PATIENT INFORMATION:

I.25 Age at diagnosis
I.6 Birth Date
I.13 Breast pain
I.7 Current age
I.29 Date of biopsy
I.26 Date of diagnosis
I.22 Date of last CBE
I.20 Date of last mammogram
I.18 Ever mammogram
I.16 Imputed patient reason for visit
I.24 Imputed personal history of breast cancer
I.10 Imputed symptoms
I.4 Information date
I.11 Lump
I.30 Lumpectomy
I.77 Managed care
I.31 Mastectomy
I.74 Medicare
I.12 Nipple discharge
I.14 Other symptoms
I.28 Personal history of biopsy
I.23 Personal history of breast cancer
I.71 Race- American Indian or Alaskan Native
I.69 Race- Asian
I. 68 Race- Black
I.70 Race-Native Hawaiian/Pacific Islander
I.72 Race-Other
I.67 Race-White
I.32 Radiation therapy
I.15 Reason for visit
I.3 Study ID
I.2 Study site
I.9 Symptoms
I.21 Time since last CBE
I.19 Time since last mammogram

II. RADIOLOGIC INFORMATION

II.31 Assessment left
II.29 Assessment overall
II.30 Assessment right
II.27 Comparison Date
II.26 Comparison film
II.18 Diagnostic views
II.10 Exam Date
II.5 Exam sequence
II.46 Facility

II.14 Imputed indication for exam
II. 13 Indication for exam
II.4 Information date
II.45 Linked
II. 24 Other procedures (non- imaging)
II.28 Physical findings
II.12 Previous mammogram date
II. 11 Reading date
II.36 Recommend additional views
II.43 Recommend Biopsy
II.42 Recommend FNA
II.40 Recommend for clinical exam
II.44 Recommend further work-up
II.32 Recommend normal interval follow-up
II.34 Recommend short term follow-up
II.41 Recommend surgical consult
II.37 Recommend ultrasound
II.33 Recommend normal interval follow-up length
II.35 Recommend short interval follow-up length
II.17 Routine views
II.3 Study ID
II.2 Study site

VI. CARCINOMA/REGISTRY INFORMATION

VI. 8 County of residence
VI.42 Extension
VI.20 Grade, differentiation
VI.4 Information Date
VI.18 Laterality
VI.26 Lymph node surgery
VI.16 Primary site
VI.25 Site specific surgery code
VI.9 State of residence
VI.3 Study ID
VI.2 Study site
VI.39 TNM M code
VI.38 TNM N code
VI.37 TNM T code
VI.36 Tumor size

VII. MALIGNANCY FOLLOW-UP INFORMATION

VII.10 Cause of death
VII.6 Date last follow-up/death
VII.8 Status at last follow-up

Attachment D

Schematic for Comparing Breast Cancer Screening Consortium Data and Medicare Data For Characterizing Women's Use Of Screening Mammography

Breast Cancer Surveillance Consortium

| | No Mammo. = Not Screened | First Mammo. (first w/in 5 yrs) | Screened 1-2 years before cancer detected | Screened 2-3 years before cancer detected | Screened 3-5 years before cancer detected |
|---|-----------------------------|---------------------------------------|--|--|--|
| No Mammogram = Not Screened | Agreement | Disagreement | Disagreement | Disagreement | Disagreement |
| First Mammo. (first w/in 5 yrs) | *A | *B | Partial Agreement | Partial Agreement | Partial Agreement |
| Screened 1-2 years before cancer detected | | Partial Agreement | Perfect Agreement | Partial Agreement | Partial Agreement |
| Screened 2-3 years before cancer detected | | *A | Partial Agreement | Perfect Agreement | Partial Agreement |
| Screened 3-5 years before cancer detected | | *A | Partial Agreement | Partial Agreement | Perfect Agreement |

Medicare

*A We will drop these cases for this comparison as the BCSC registries are not 100% population-based and may thus under-ascertain mammography use in the 3 communities/statistics included in the analysis. However, in our final analysis we will use the Medicare data characterization of these mammograms.

*B These women with breast cancer have their only mammogram around the time of their breast cancer diagnosis. The algorithm described in attachment E will be used to further characterize these examinations.

Attachment E

Schematic for Assessing Agreement Between Breast Cancer Screening Consortium Data and Medicare Data For Each Mammogram

Breast Cancer Surveillance Consortium

| | No Mammogram | Diagnostic | Prob. Diagnostic | Screened w/ a breast mass | Prob. Screened | Screening |
|-------------------------|--------------|-------------------------|-------------------------|---------------------------|----------------|--------------|
| No Mammogram | Agreement | Agreement* ^C | Agreement* ^C | Disagreement | Disagreement | Disagreement |
| Diagnostic | *A | Agreement | Agreement | Agreement | Disagreement | Disagreement |
| Peri-cancer Mammo. Only | | *B | *B | *B | *B | *B |
| Screening | | Disagreement | Disagreement | Agreement | Agreement | Agreement |

Medicare

*A We will drop these cases for this comparison as the BCSC registries are not 100% population-based and may thus under-ascertain mammography use in the 3 communities/statistics included in the analysis. However, in our final analysis we will use the Medicare data characterization of these mammograms.

*B We will use modeling to try to "adjust" Medicare data based on BCSC data as the "gold standard". This will be estimated using half the data, and tested using the second half of the data.

*C The goal of the algorithm is to determine if mammograms were obtained as a screening exam or not. For this comparison, "no mammogram" is equivalent to a diagnostic mammogram.

Attachment F

MAMMOGRAPHY IN ELDERLY WOMEN

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